

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1240

[Docket No. 2003N-0400]

RIN 0910-ZA21

Centers for Disease Control and Prevention

42 CFR Part 71

Control of Communicable Diseases; Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals

AGENCIES: Centers for Disease Control and Prevention, Food and Drug Administration (HHS).

ACTION: Interim final rule; opportunity for public comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are issuing this interim final rule to amend their regulations to establish new restrictions and modify existing restrictions on the import, capture, transport, sale, barter, exchange, distribution, and release of African rodents, prairie dogs, and certain other animals. We are taking this action to prevent the spread of monkeypox, a communicable disease, in the United States.

DATES: The interim final rule is effective on [insert date of publication in the FEDERAL REGISTER]. Submit written or electronic comments on this interim final rule by [insert date 75 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: For FDA: Send written comments on the rule and on the information collection to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630

7MB
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Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

<http://www.fda.gov/dockets/ecomments>.

For CDC: Send written comments on the information collection to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Rd., MS E11, Atlanta, GA 30333. Comments on the rule itself should be sent to FDA's Division of Dockets Management (see FDA addresses).

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. What Is Monkeypox, and How Did It Spread in the United States?

Monkeypox is a rare, zoonotic, viral disease that occurs primarily in the rain forest countries in central and west Africa. (A zoonotic disease is a disease of animals that can be transmitted to humans under natural conditions.) The illness was first noted in monkeys in 1958 (which explains its name), but, in Africa, serologic evidence of monkeypox infection has been found in many other species, including some species of primates, rodents, and lagomorphs (which includes such animals as rabbits). African rodents are considered to be the most likely natural host of the monkeypox virus (Ref. 1).

In humans, monkeypox is marked by rashes that are similar to those seen in smallpox; other signs and symptoms include a temperature at or above 99.3 degrees, chills and/or sweats, headache, backache, lymphadenopathy (a disease of the lymph nodes), sore throat, cough, and shortness of breath (Ref. 2). The disease's incubation period is approximately 12 days (Ref. 3). In Africa, monkeypox has a mortality rate in humans ranging from 1 to 10 percent.

As of July 8, 2003, there have been 35 laboratory-confirmed cases of monkeypox in people in the United States, and about another three dozen suspect and probable cases under investigation, in Illinois, Indiana, Kansas, Ohio, Missouri, and Wisconsin (Ref. 4). As of July 11, 2003, 16 persons were reported to have been hospitalized; however, some of these hospitalizations were for isolation purposes unrelated to illness. Among those hospitalized, two were children who required intensive care, one for severe monkeypox-associated encephalitis (encephalitis is an inflammation of the brain), and one with profound painful cervical and tonsillar adenopathy (adenopathy refers to an enlargement of the glands) and diffuse pox lesions, including lesions in the oropharynx. Both children recovered from their illness.

In the United States, individuals apparently began contracting monkeypox in early May, 2003, primarily as a result of contact with prairie dogs that had contracted monkeypox from diseased African rodents. Investigations indicate that a Texas animal distributor imported a shipment of approximately 800 small mammals from Ghana on April 9, 2003, and that shipment contained 762 African rodents, including rope squirrels (Funiscuirus sp.), tree squirrels (Heliosciurus sp.), Gambian giant pouched rats (Cricetomys sp.), brushtail porcupines (Atherurus sp.), dormice (Graphiurus sp.), and striped mice (Hybomys sp.). Some animals were infected with monkeypox, and CDC laboratory testing confirmed the presence of monkeypox in several rodent species, including one Gambian giant pouched rat, three dormice, and two rope squirrels (Ref. 4). Of the 762 rodents from the original shipment, 584 have been traced to distributors in six states. A total of 178 African rodents could not be traced beyond the point of entry in Texas because records were not available (Ref. 4). The number of animals traced may change as the investigation continues.

II. What Actions Have Been Taken to Prevent the Spread of Monkeypox?

Non-native animal species, such as the African rodents, can create serious public health problems when they introduce a new disease, such as monkeypox, to the native animal and human populations. The transportation, sale, or distribution of an infected animal, or the release of an infected animal into the environment can result in the further spread of disease to other animal species and to humans.

Several States have issued orders or emergency rules to prohibit the importation, sale, distribution, release, disposal, and/or display of prairie dogs and certain rodents (Refs. 5 through 11). However, these State efforts are limited to their respective jurisdictions, and some State orders or rules expire on a specific date, while others differ in the types of animals and actions

that are covered. Communicable diseases, such as monkeypox, are not confined by State borders and, as shown by the presence of the monkeypox virus in prairie dogs, may affect multiple animal species. Consequently, Federal action was necessary to help prevent the spread of monkeypox. On June 11, 2003, the Director of CDC and the Commissioner of Food and Drugs, under 42 CFR 70.2 and 21 CFR 1240.30 respectively, issued a joint order (Ref. 12) prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of:

- Prairie dogs (Cynomys sp.);
- Tree squirrels (Heliosciurus sp.);
- Rope squirrels (Funisciurus sp.);
- Dormice (Graphiurus sp.);
- Gambian giant pouched rats (Cricetomys sp.);
- Brush-tailed porcupines (Atherurus sp.), and
- Striped mice (Hybomys sp.).

The June 11, 2003, order did not apply to the transport of these animals to veterinarians or animal control officials or other entities under guidance or instructions issued by Federal, State, or local government authorities. In addition, under 42 CFR 71.32(b), CDC implemented an immediate embargo on the importation of all rodents from Africa (order Rodentia).

Both CDC and FDA are also working closely with other Federal agencies, such as the Animal and Plant Health Inspection Service (APHIS) in the Department of Agriculture (USDA), the Fish and Wildlife Service (FWS) in the Department of the Interior, Customs and Border Protection in Department of Homeland Security, and the Department of Transportation. FDA

and CDC are also working with numerous State and local agencies to prevent further exposure of animals and people to the monkeypox virus.

III. What Does The Interim Final Rule Do?

A. Why Are FDA and CDC Issuing an Interim Final Rule?

We issued the June 11, 2003, order to address quickly what was then a new and rapidly developing monkeypox outbreak (Ref. 13). We now are able to provide a more detailed set of measures aimed at creating a regulatory approach to prevent the monkeypox virus from becoming established and spreading in the United States, with exemption procedures to accommodate special circumstances, and are doing so by issuing this interim final rule. This interim final rule supersedes the June 11, 2003, order. As appropriate, we will amend the interim final rule in response to comments and to any new developments in the monkeypox outbreak.

This interim final rule creates two complementary regulations. First, with respect to certain animals that are in the United States, the interim final rule adds 21 CFR 1240.63, entitled “African rodents and other animals that may carry the monkeypox virus.” FDA will enforce 21 CFR 1240.63. Second, for African rodents that are being imported or offered for import to the United States, the interim final rule adds 42 CFR 71.56, that is also entitled “African rodents and other animals that may carry the monkeypox virus.” CDC will enforce 42 CFR 71.56. Together, 21 CFR 1240.63 and 42 CFR 71.56 are intended to prevent the establishment and spread of the monkeypox virus in the United States.

Section 361 of the Public Health Service Act (PHS act) (42 U.S.C. 264) serves as the legal authority for both 21 CFR 1240.63 and 42 CFR 71.56. Section 361 of the PHS act gives the Secretary of Health and Human Services the authority to make and enforce regulations to

prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the States or from one State to another State. As we explain in section IV of this document, both FDA and CDC have issued regulations under section 361 of the PHS act, and several FDA regulations are similar or identical to CDC regulations. Here, however, the responsibilities are being divided between our two agencies. FDA's regulation focuses on animals moving between and within States while CDC's regulation focuses on imported animals. Our goal in creating separate FDA and CDC regulations is to use our limited resources to deal with the current monkeypox situation in the most efficient manner possible.

B. What Does FDA's Rule Say?

1. Where Is the Rule Codified? (21 CFR 1240.63)

As we stated in section III.A of this document, the interim final rule adds 21 CFR 1240.63, entitled "African rodents and other animals that may carry the monkeypox virus."

2. What Does the Rule Prohibit? (21 CFR 1240.63(a))

21 CFR 1240.63(a)(1) contains several general prohibitions. In brief, under 21 CFR 1240.63(a)(1)(i), regardless of your status (such as a pet dealer, pet owner, researcher, animal trapper, zoological park administrator, etc.), you must not capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment:

- Prairie dogs (Cynomys sp.),
- African Tree squirrels (Heliosciurus sp.),
- Rope squirrels (Funisciurus sp.),
- African Dormice (Graphiurus sp.),

- Gambian giant pouched rats (Cricetomys sp.),
- Brush-tailed porcupines (Atherurus sp.),
- Striped mice (Hybomys sp.), or
- Any other animal so prohibited by order of the Commissioner of Food and Drugs

because of that animal's potential to transmit the monkeypox virus.

For convenience, this preamble will refer to the above animals as "listed animals."

The interim final rule covers the listed animals because animals from those species have been associated, either directly through laboratory tests or indirectly through epidemiological evidence, in the current outbreak of the monkeypox virus in humans (Ref. 14). In general, the animals identified in 21 CFR 1240.63 are the same as those listed in the CDC-FDA order dated June 11, 2003, except that the rule also refers to other, yet-unspecified kinds of animals that the Commissioner of Food and Drugs may prohibit by order. FDA included the latter "catch-all" provision in § 1240.63 because the agency cannot preclude the possibility that monkeypox may spread to other animal species, and, if monkeypox is found in other animals, FDA needs to be able to list those animals quickly. FDA derives its authority to list such animals by order from section 361 of the Public Health Service Act, which is the same statutory authority under which it is issuing this interim final rule. This statutory provision authorizes the Secretary to make and enforce regulations to prevent the introduction, transmission, and spread of communicable diseases. Section 1240.63(b)(1) of the interim final rule (which we discuss later in this section) allows FDA to issue orders causing such animals to be quarantined or destroyed and to "take any other action necessary to prevent the spread of the monkeypox virus." Such "other actions" may include issuing orders necessary to prevent the spread of monkeypox. An order adding animals to those "listed animals" that have the potential to transmit the monkeypox virus is such an order

since control of animals that may transmit monkeypox is necessary to prevent the spread of this communicable disease.

The interim final rule prohibits capture, offers to capture, transport, offers to transport, sale, barter, or exchange, offers to sell, barter, or exchange distribution, offers to distribute, or release of a listed animal into the environment regardless of whether the activity is interstate or intrastate. The June 11, 2003, order referred to “transportation in interstate commerce.” This created some confusion about whether the order applied to activities occurring within a State. In this interim final rule, FDA makes clear that the restrictions apply to both interstate and intrastate activities. The interim final rule must reach intrastate activities because FDA cannot effectively prevent interstate transmission of communicable disease without addressing intrastate transmission. This is due to the fact that an infected animal could transmit the monkeypox virus to other animals within a State, and eventually and inevitably the monkeypox virus would be transmitted to other States as infected wild animals or even infected, domesticated animals crossed State borders. Effective intrastate controls are, therefore, an integral part of efforts to prevent interstate transmission of communicable disease.

21 CFR 1240.63(a)(1)(i) also prohibits the capture and offers to capture listed animals. For purposes of this rule, “capture” means the act of catching or confining an animal in the wild with the intent of removing that animal for sale, barter, or exchange, distribution, and/or release into the environment. So, for example, 21 CFR 1240.63(a)(1)(i) prohibits a person from taking prairie dogs from their burrows for purposes of selling those prairie dogs, but it would not consider the act of immobilizing a prairie dog, taking measurements or biological samples (such as blood samples), and then releasing the prairie dog as constituting “capture.” Similarly, if a prairie dog escaped from its cage in a pet store, catching the prairie dog to put it back in its cage

would not constitute “capture” within 21 CFR 1240.63(a)(1)(i). As another example, individuals sometimes shoot prairie dogs because their burrows may present a hazard to cattle and horses; shooting a prairie dog would not constitute “capture” within 21 CFR 1240.63(a)(1)(i). We recommend that you dispose of dead prairie dogs appropriately in consultation with State wildlife control officials and following applicable CDC guidance. The prohibition against capture and offers to capture is an appropriate and logical extension of the June 11, 2003, order because, for example, it would be illogical to prohibit wild prairie dogs from being transported, but still allow them to be captured. An infectious animal could transmit the monkeypox virus to humans during its capture, just as it could transmit the monkeypox virus when a human handled the animal during transport. Therefore, the interim final rule prohibits the capture of listed animals and offers to capture such animals.

Furthermore, 21 CFR 1240.63(a)(1)(i) prohibits the distribution of listed animals. Prohibiting distribution is another appropriate and logical extension of the June 11, 2003, order. The June 11, 2003, order prohibited, in relevant part, “offering for commercial or public distribution,” yet was silent regarding the actual distribution of listed animals. To clarify FDA’s intent, 21 CFR 1240.63(a)(1)(i) prohibits the distribution of listed animals in addition to the other prohibitions. FDA has also simplified the rule by prohibiting offers to distribute listed animals rather than “offers for commercial or public distribution” that were in the June 11, 2003, order. The June 11, 2003, order made no distinction between “commercial or public distribution” and other types of distribution, nor did it indicate that non-commercial or nonpublic distribution presented lesser risk of transmitting the monkeypox virus. Consequently, 21 CFR 1240.63(a)(1)(i) now states, in relevant part, that you must not “offer to distribute” a listed animal.

21 CFR 1240.63(a)(1)(i) also prohibits “sale, barter, or exchange” and “offers to sell, barter, or exchange” listed animals. Animals are sometimes traded or exchanged at “swap meets,” and such trades or exchanges might not be considered to be “sales.” Therefore, 21 CFR 1240.63(a)(1)(i) prohibits the sale, barter, or exchange of listed animals and offers to sell, barter, or exchange listed animals.

FDA wishes to clarify that 21 CFR 1240.63 applies regardless of whether an animal is alive or dead. Dead animals could still harbor the monkeypox virus and could be infectious, so the agency cannot ignore such dead animals as a potential source for infection. Therefore, to protect the public health to the best extent possible, 21 CFR 1240.63(a)(1)(i) pertains to dead animals.

21 CFR 1240.63(a)(1)(ii) states that you must not prevent or attempt to prevent FDA from causing a listed animal to be quarantined or destroyed pursuant to a written order for the animal’s quarantine or destruction. (For purposes of this rule, “quarantine” means that the animal is held or stored in an isolated area, and all further movement has been restricted so as not to expose other animals.) Although most individuals will cooperate with a written order to destroy an infected animal, some individuals may want to avoid causing an animal’s destruction by releasing the animal instead (Ref. 15). Releasing an infected or potentially infected animal would create a serious risk to animal and human health because the monkeypox virus could then spread to domestic animal species and to humans and could become established in the United States. Therefore, if you prevent or attempt to prevent FDA from causing an animal to be quarantined or destroyed, you may be subject to criminal penalties. Penalties are discussed in part IV below.

FDA repeats that prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release of listed animals is vital to prevent the monkeypox virus from becoming established and spreading in the United States. Nevertheless, the agency also recognizes that there are limited circumstances warranting exemptions from some prohibitions, such as the need to transport an animal for zoological, educational, medical, scientific, or other purposes. Consequently, 21 CFR 1240.63(a)(2) allows you to:

- Transport a listed animal to a veterinarian or animal control official for veterinary care, quarantine, or destruction purposes; and
- Capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release a listed animal into the environment after receiving written permission from FDA. Section 1240.63(a)(2)(ii) states, however, that you may not seek written permission to sell, barter, exchange, or offer to sell, barter, or exchange a listed animal as a pet. We do not intend to permit pet sales (or barter or exchange) because the monkeypox outbreak developed in the pet industry, and exposure to infected animals intended as pets led to infections in prairie dogs. The infected prairie dogs, in turn, infected humans. Thus, compared to animals in the wild pets present a greater potential risk for transmitting the monkeypox virus.

To illustrate when transport of a listed animal to a veterinarian or animal control official would be allowed, assume that an individual has a prairie dog that appears to be ill. Section 1240.63(a)(1)(i) would prohibit transportation of that animal, yet, under 21 CFR 1240.63(a)(2)(i), an individual could transport the prairie dog to a veterinarian for treatment. As

another example, individuals might shoot prairie dogs because their burrows present a hazard to cattle and horses. In such a situation, 21 CFR 1240.63(a)(1)(i) would prohibit transportation of the prairie dog carcasses. However, under 21 CFR 1240.63(a)(2)(i), an individual could transport the prairie dog carcasses to animal control officials for incineration or other appropriate means of disposal.

21 CFR 1240.63(a)(2)(ii)(A) describes the procedures for seeking written permission from FDA. 21 CFR 1240.63(a)(2)(ii)(B) requires you to state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. For example, the description of the animals involved should identify the animal(s) and discuss the number of animals involved, their environment, and health conditions. The explanation of your reasons for seeking an exemption should show the justification, including need and benefits, relating to the requested exemption (such as public health reasons, scientific research, ecological reasons, etc.). FDA will grant exemptions on a case-by-case basis and only for specific purposes and in specific circumstances. Thus, for example, if you receive written permission to transport prairie dogs from city A to city B, but you later want to move the same prairie dogs to a third location, city C, you would have to seek written permission to move the prairie dogs from city B to city C. Depending on the number and nature of exemption requests it receives, FDA may publish a guidance document to describe the types of information

it would like to see in an exemption request. Under 21 CFR 1240.63(a)(2)(ii)(C), FDA will respond, in writing, to all requests, and it also may impose conditions in granting an exemption. If FDA decides against granting written permission, that decision could be reviewed under 21 CFR 10.75 (“Internal agency review of decisions”).

To illustrate when a person might seek written permission from FDA, the agency notes that efforts to reintroduce black-footed ferrets into certain areas may depend on the ability to transport wild prairie dogs and release them into the environment (Ref. 16). The black-footed ferrets use prairie dog burrows for shelter and also feed on prairie dogs. Thus, in this example, biologists working to reintroduce black-footed ferrets would seek written permission from FDA to capture, transport, and release prairie dogs in connection with each black-footed ferret program. They would also remain subject to any other Federal, State, local or tribal requirements.

In the previous example, the efforts involving the black-footed ferrets may have been the subject of other Federal and State permits. We acknowledge that the June 11, 2003, order stated that its prohibitions did not apply to persons who transport listed animals to veterinarians or animal control officials “or other entities pursuant to guidance or instructions issued by federal, State, or local government authorities.” The order’s reference to Federal, State, and local government authorities has created some confusion as to whether any Federal or State permit issued before June 11, 2003, constituted “guidance or instructions” that would create an exception to the order. Through this interim final rule, we are clarifying that we do not consider all Federal, State, or local government permits as automatically creating an exception to the prohibitions against transport, sale, etc., because we have no assurance that such Federal, State, or local government permits provide adequate safeguards to prevent the spread of the

monkeypox virus. Therefore, 21 CFR 1240.63(a)(2)(ii) requires you to obtain written permission from FDA to capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release a listed animal into the environment.

We also acknowledge that 21 CFR 1240.63(a)(2)(ii) appears to conflict with a position that we took on July 2, 2003, in a document titled, “Wild-to-Wild Translocation or Transportation of Prairie Dogs” (“Wild-to-Wild document”) (Ref. 17). The Wild-to-Wild document was intended to address situations where a wild population of prairie dogs would be relocated to another wild habitat, and the document suggested that States that have not been implicated in the monkeypox outbreak issue guidance or instructions for translocating prairie dogs within a State, and it listed the States that had been implicated in the monkeypox outbreak as of June 27, 2003. The Wild-to-Wild document was interpreted as giving State and local governments in nonimplicated States the ability to decide on translocating prairie dogs without having to obtain an exemption from FDA or CDC. However, the policies expressed in the Wild-to-Wild document have caused some uncertainty, particularly as some States have been listed as being affected by the monkeypox virus, and then “de-listed.” For example, if a person began translocating prairie dogs in a non-listed State, but the State was then listed before the translocation process could be completed, should that person seek an exemption from FDA for those prairie dogs that had not been translocated before the State was listed? Or could the person complete the translocation process without an exemption from FDA because the translocation process began when the State was not listed? The Wild-to-Wild document also created the potential for conflicting policies between States. For example, one State could adopt strict criteria to ensure that certain safeguards were observed, while a neighboring State could have no

criteria at all and decide on wild-to-wild translocations on an ad hoc basis. Given these issues and potential problems, we have decided that the written permits in 21 CFR 1240.63(a)(2)(ii)(B) must be obtained and will no longer observe the policies expressed in the Wild-to-Wild document. In other words, all wild-to-wild translocations or transportation of prairie dogs, other than those that occurred before the date of this interim final rule, will need a written permit under 21 CFR 1240.63(a)(2)(ii)(B), and the interim final rule supersedes the Wild-to-Wild document.

3. What Actions Can FDA Take? (21 CFR 1240.63(b))

FDA has limited knowledge as to which kinds of animals in the United States may be vulnerable to the monkeypox virus, but it is extremely difficult, if not impossible, to eradicate a virus once it becomes established in a country or region. For example, the West Nile virus was unknown in the United States before 1999. The virus apparently arrived in the eastern United States and quickly spread, via mosquitoes, to domestic bird species, other animal species (such as horses), and to humans. In 1999, the virus was reported in 4 States; by October 2003, 45 States had reported cases of the West Nile virus activity in humans or other animals. The virus's continued spread in the United States suggests that it is now permanently established in the United States.

To prevent the monkeypox virus from spreading and becoming established in the United States, 21 CFR 1240.63(b)(1) authorizes FDA to take the following actions:

- Issue an order causing an animal to be placed in quarantine. An order causing an animal to be placed in quarantine could extend to kinds of animals not named in this interim final rule. For example, if a potentially infected prairie dog had been

in contact with a ferret, it would be reasonable to quarantine the ferret to ensure that it was not infected with the monkeypox virus;

- Issue an order causing an animal to be destroyed; and
- Take other actions as necessary to prevent the spread of the monkeypox virus.

For example, if a pet store were going out of business, FDA could, under the interim final rule, make arrangements with the appropriate Federal, State, local and tribal authorities to take temporary possession of the animals.

21 CFR 1240.63(b)(1) also states that the authority to issue these orders or to take any other action is “in addition to any other authorities in this part.” The reference to other authorities includes, for example, 21 CFR 1240.30, which allows FDA to take measures to prevent the spread of communicable disease, “including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.”

FDA will issue all orders in writing. The order will contain other details, such as the animals covered by the order, your ability to appeal the order (including instructions on filing an appeal), and any other conditions on quarantine or destruction. FDA officials ordinarily will not themselves quarantine or destroy an animal. Instead, FDA officials will order that the animal be quarantined or destroyed, and the individual receiving the order will be responsible for placing the animal in quarantine or having it destroyed and any costs associated with quarantining or destroying the animal. CDC has issued guidance to animal health officials on the disposition of animals (Refs. 18 and 19).

Additionally, there may be instances where it is difficult to identify an animal as belonging to a particular species. Some species may resemble another, and juvenile animals

may look different from adult animals. Thus, if you capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, or offer to distribute any rodent, FDA strongly advises you to take steps to accurately and reliably identify the species involved. Accurate and reliable identification will reduce the potential for disagreements as to whether an animal or group of animals is or should be subject to an order and avoid potential, unfortunate instances where animals that cannot be readily identified or whose species identification is in dispute are included in an order to cause their destruction.

If a person violates 21 CFR 1240.63, that person may be subject to fines, imprisonment, and inspections. Penalties for violating the rule are discussed in section IV of this document.

4. Can You Appeal an Order? (21 CFR 1240.63(c))

If you receive a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed, 21 CFR 1240.63(c) allows you to appeal that order. Your appeal must be in writing and be submitted to FDA within 2 business days after you receive the order. As part of your appeal, you may request an informal hearing, and your appeal must include specific facts showing there is a genuine and substantial issue of fact that requires a hearing. For example, if the order was to cause the destruction of prairie dogs, and you have beavers instead of prairie dogs, a genuine and substantial issue of fact (i.e., whether you have the animals described in the order) would exist. In contrast, if the order was to cause the destruction of prairie dogs, and you simply disagreed with the idea of destroying any animal, there would be no genuine and substantial issue of fact, and FDA would not conduct a hearing for your appeal. The interim final rule instructs you to send your appeal to the FDA District Director whose office issued the order.

If FDA grants your request for an informal hearing, FDA will follow the regulatory hearing requirements at 21 CFR part 16, except that the written order will serve as notice of opportunity for a hearing for purposes of initiating the hearing under 21 CFR 16.22(a). Additionally, 21 CFR 1240.63(c)(3) states that the presiding officer will issue a decision instead of issuing a report and a recommended decision as would normally be required under 21 CFR 16.60(e) and (f). (Under pre-existing FDA regulations, the Commissioner of Food and Drugs may delegate the authority to an FDA employee to serve as the presiding officer (see 21 CFR 16.42(a).) The interim final rule gives the presiding officer the authority to issue a decision so that the agency may deal with infected or potentially infected animals quickly; otherwise, if the presiding officer were to issue reports and recommendations, final action on an animal's status would be delayed, and this would increase the possibility that the animal, if infected, could escape or otherwise transmit the monkeypox virus to humans or other animals.

FDA has also amended 21 CFR 16.1(b)(2) to add 21 CFR 1240.63 to the list of regulatory provisions for which a part 16 regulatory hearing is available.

C. What Does CDC's Rule Say?

1. Where Is the Rule Codified? (42 CFR 71.56)

The interim final rule creates a new 42 CFR 71.56 titled, "African rodents and other animals that may carry the monkeypox virus."

2. What Does the Rule Prohibit? (42 CFR 71.56(a))

42 CFR 71.56(a) contains only two general prohibitions. In brief, under 42 CFR 71.56(a)(1)(i), you must not import or offer to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa; any products derived from such rodents, any other animal, whether dead or alive, whose importation the

Director of CDC has prohibited by order, or any products derived from such animals. This provision is intended to prevent the further importation of infected and potentially-infected rodents and represents a slight modification from the import restriction that appeared in the June 11, 2003, order. The June 11, 2003, order barred importation of “all rodents from Africa.” The rule’s import prohibition is intended to make clear that it covers any rodents that were caught in Africa and then shipped directly to the United States or shipped to other countries before being imported to the United States. The prohibition also applies to rodents whose native habitat is in Africa, even if those rodents were born elsewhere. For example, 42 CFR 71.56(a)(1)(i) would apply to a Gambian giant pouched rat even if that animal was born outside Africa. A broad import ban on African rodents is necessary because there is no quick, practical method for determining whether a specific animal was born in a particular geographic region. The import restriction complements efforts taken by the U.S. Fish and Wildlife Service to prevent the importation of infected animals (Ref. 20).

Similarly to 21 CFR 1240.63, 42 CFR 71.56 applies to dead animals. Some individuals have attempted to conceal “bushmeat” (a term used to describe meat obtained from animals taken in the wild or the “bush”) from Federal authorities since the June 11, 2003, order was issued and others have attempted to import preserved specimens of listed species. The monkeypox virus can remain infectious in bushmeat (Refs. 1, 21, and 38), and CDC is unaware of data demonstrating the safety of raw or even prepared bushmeat. Preparation methods such as smoking, salting, or brining bushmeat may slow down bushmeat’s decay, but may not render bushmeat free of infectious agents. Therefore, 42 CFR 71.56(a)(1) applies to live and dead African rodents.

42 CFR 71.56(a)(1)(ii) states that you must not prevent or attempt to prevent CDC from causing an animal to be quarantined, re-exported, or destroyed pursuant to a written order for that animal's quarantine, re-export, or destruction. (For purposes of this rule, "quarantine" means that the animal is held or stored in an isolated area, and all further movement has been restricted so as not to expose other animals.) Most individuals will cooperate with a written order to quarantine, re-export, or destroy an infected animal, but some individuals may attempt to avoid those consequences by releasing the animal instead. Releasing an infected or potentially infected animal would create a serious risk to animal and human health because the monkeypox virus could then spread to native animal species and become established in the United States. Therefore, if you prevent or attempt to prevent us from causing an animal to be quarantined, re-exported, or destroyed, you may be subject to criminal penalties. (For more information on penalties, section IV of this document.)

Similarly to 21 CFR 1240.63(a)(2), 42 CFR 71.56(a)(2) recognizes that there are limited circumstances warranting exemptions from some prohibitions. Consequently, under 42 CFR 71.56(a)(2), an individual may seek written permission from CDC to import any rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or any other kind of animal whose importation the Director has prohibited by order. The interim final rule describes the procedures for seeking written permission from CDC and the information that should be submitted with any request and also states that the request must be limited to scientific, exhibition (such as exhibition of an animal at a zoo), or educational purposes. CDC is limiting the request to scientific, exhibition, or educational purposes because it recognizes the important contributions that these rodents may make to science, education, and conservation. CDC will respond, in writing, to all requests, and it also may impose conditions in granting an

exemption. If CDC decides against granting written permission, that decision may be appealed by writing to the CDC official whose office denied the request. The appeal must state the reasons for the appeal and show there is a genuine and substantial issue of fact in dispute. CDC will issue a written response to the appeal which will constitute final agency action.

42 CFR 71.56(a)(3) represents another exemption from the import restrictions. Some individuals have asked whether they could import taxidermied animals or animal trophies, while other questions have involved products derived from animals, such as brushes that use animal hair and animal skins. Products derived from rodents, such as products that use rodent hair, quills, bones, and skins, may contain viable monkeypox virus if the animal from which they are derived was infected with monkeypox. This is based on the fact that variola virus, a related pox virus, has been shown to remain viable in proteinaceous exudates for as long as 1 year (Ref. 22). If these products are properly processed to render them noninfectious, they pose no disease risk. Such processes would include inactivation by:

- Heat (heated to an internal temperature of 70 °C or placed in boiling water for a minimum of 30 minutes);
- Preservation in 2 percent formaldehyde;
- Chemically treating in acidic or alkaline solutions (soaking in a solution below pH 3.0 or above pH 11.5 for 24 hours); or
- The use of hypertonic salts.

Vaccinia virus, a related pox virus, was shown to be inactivated after heating in neutral salt buffer solution for 90 minutes at 50 °C or after heating for 60 minutes at 55 °C (Ref. 23).

Support for these methods can be found in the pox virus material safety data sheet compiled by Health Canada, <http://www.hc-sc.gc.ca/pphb-dgspsp/msds-ftss/msds160e.html>, which states that

pox viruses are rendered nonviable by 2 percent formaldehyde, and heating to >60 °C.

Procedures for alkaline and acid inactivation are based on the OIE 2003 Terrestrial Animal Code procedures for food and mouth disease (Article 3.6.2.1)

(http://www.oie.int/eng/normes/MCode/A_00144.htm). (FDA has verified the Web site address,

but FDA is not responsible for any subsequent changes to the Web site after this document

publishes in the FEDERAL REGISTER.) Products derived from African rodents, if treated

using one of these methods, are not subject to the import prohibition at 42 CFR 71.56(a)(1) and

may be imported without written permission from CDC. Similarly, fully taxidermied African

rodents and completely finished trophies present no disease risk and therefore may be imported

without written permission from CDC. Products imported under the exception in 42 CFR

71.56(a)(3) are subject to inspection to ensure that they do meet the conditions set forth in 42

CFR 71.56(a)(3).

3. What Actions Can CDC Take? (42 CFR 71.56(b))

To prevent the monkeypox virus from spreading and becoming established in the United States, 42 CFR 71.56(b) gives CDC the authority to:

- Issue an order causing an animal to be placed in quarantine;
- Issue an order causing an animal to be re-exported;
- Issue an order causing an animal to be destroyed; or
- Take any other action necessary to prevent the spread of the monkeypox virus.

The Director of CDC can also use other authorities to help prevent the spread of monkeypox. For example, under 42 CFR 71.32(b), if the Director has reason to believe that there is an article (including an animal) arriving at a United States port and that article is or may be infected with a communicable disease, the Director may require such actions as detention,

disinfection, or other related measures necessary to prevent the introduction, transmission, or spread of communicable disease. Consequently, 42 CFR 71.56(b) recognizes that the Director may use other authorities, and states that the authority to issue orders or to take other action is “in addition to any other authorities under this part.”

Any orders issued by CDC, similar to those issued by FDA, will be in writing and will contain other details, such as the animals covered by the order, the ability to appeal an order, and any other conditions on quarantine, re-export, or destruction. CDC officials ordinarily will not themselves quarantine, re-export, or destroy an animal. Instead, CDC officials will order that the animal be quarantined, re-exported, or destroyed, and the individual receiving the order will be responsible for placing the animal in quarantine or having it re-exported or destroyed and be responsible for any costs associated with quarantining, re-exporting, or destroying the animal. CDC has issued guidance to animal health officials on the disposition of animals.

CDC emphasizes that there may be instances where it is difficult to identify an animal as belonging to a particular species. Some species may resemble another, and juvenile animals may look different from adult animals. Thus, if you import any rodent, CDC strongly advises you to take steps to accurately and reliably identify the species involved. Accurate and reliable identification will reduce the potential for disagreements as to whether an animal is or should be subject to an order and avoid potential, unfortunate instances where animals that cannot be readily identified or whose species identification is in dispute are included in an order to cause their destruction.

4. Can You Appeal an Order? (42 CFR 71.56(c))

If you received a written order to cause an animal to be placed in quarantine, re-exported, or destroyed, 42 CFR 71.56(c) explains that you may appeal that order. Your appeal must be in

writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. CDC will issue a written response to the appeal which will constitute final agency action.

D. When Does the Rule Become Effective?

For the effective date of the interim final rule see the DATES section of this document.

E. Will We Revoke Or Amend the Rule if Monkeypox Is Eradicated in the United States?

Monkeypox is endemic in parts of Africa. Therefore, we do not anticipate revoking the prohibition on import of African rodents and any other animals that the Director of CDC has specified under 42 CFR 71.56(a)(1)(i). However, FDA will revoke or amend, as warranted, all or parts of 21 CFR 1240.63 if FDA concludes that monkeypox is eradicated or adequately controlled so that the virus does not become established in the United States. FDA's decision would depend on scientific principles for controlling zoonotic diseases. For example, if the incubation period is known, then it would be prudent to continue the restrictions for a time period that is double the incubation period to ensure that there is little further risk of infection or restarting the monkeypox outbreak. CDC tests on some animals involved in the original April 9, 2003, shipment from Ghana suggest that, insofar as dormice are concerned, the incubation period may be as long as 2.5 months. If FDA rounds this time frame up to 3 months, and then doubles the incubation period, there would appear to be little further risk of infection after 6 months had passed with no further evidence of monkeypox identified, and FDA would be able to take actions to revoke or amend 21 CFR 1240.63. The last infected animal from the April 9, 2003, shipment that died from monkeypox died on July 20, 2003. There have been no identified

monkeypox cases in animals or people in the United States since that date. If no further monkeypox cases are identified in the United States, and if there is no new information warranting an extension of the 6-month time period, FDA intends to revoke or amend 21 CFR 1240.63 as early as January 20, 2004, which will be 6 months after July 20, 2003. At that time, if FDA decided to revoke or amend 21 CFR 1240.63, it would publish an appropriate document (such as a proposed rule or direct final rule) in the FEDERAL REGISTER. FDA invites comments on this approach.

We emphasize that any possible revocation or amendment of 21 CFR 1240.63 may also depend on new data or new developments. For example, various animal studies are being conducted to learn more about the incubation period and transmission dynamics of monkeypox. If those studies suggest that the period for incubation and transmission may be longer than 2.5 months, FDA could decide to recalculate the date on which it might revoke or amend 21 CFR 1240.63. Studies are also underway to determine whether certain species that may be infected with the virus, but not display any symptoms, can infect other species. To illustrate how the virus could spread from an asymptomatic animal, assume that an animal can carry the monkeypox virus, but that the animal does not develop monkeypox. If that animal later comes into contact with prairie dogs, a species which is already known to be susceptible to monkeypox, then the prairie dogs could become infected, and another monkeypox outbreak in prairie dogs could erupt. Again, if studies suggest that species can be asymptomatic, but still infectious, those results could cause FDA to recalculate the date on which it could revoke or amend 21 CFR 1240.6.

F. What Actions Can be Taken to Prevent Outbreaks of Other Zoonotic Diseases?

If another outbreak of a different zoonotic disease occurred in the United States, we

would take actions comparable to those we have taken to address monkeypox, modifying those actions as appropriate to the new circumstances. However, we believe that the introduction of monkeypox into the United States shows that we need to develop measures to prevent or minimize the likelihood of other zoonotic disease introductions or outbreaks. As noted in section IV of this document, section 361 of the PHS Act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see State of Louisiana v. Mathews, 427 F. Supp. 174 (E.D. La. 1977)). We may, therefore, publish a document in the FEDERAL REGISTER that would discuss possible regulatory approaches, such as:

- Banning the import into the United States, as well as the capture, sale and distribution within the United States, of certain categories of: Animals (e.g., rodents, marsupials, and bats), or animals captured in the wild, or animals captured in the wild from certain regions of the world, including regions within the United States (e.g., prairie dogs in the United States due to their potential to carry plague or tularemia); or
- Requiring health certifications and subsequent quarantine and health examination and/or testing prior to import or domestic distribution of certain categories of animals; or
- Requiring assessments of potential disease risks prior to import or domestic distribution of certain categories of animals, with the imposition of conditions or restrictions depending on the level of risk presented.

If we decide to publish a document in the FEDERAL REGISTER that addresses the broader issues of zoonotic diseases and exotic species, that document will provide an opportunity for public comment on those issues.

IV. What Is the Legal Authority for This Rulemaking?

Because the public health objective is to prevent the spread of communicable disease, we are issuing the rule under section 361 of the Public Health Service Act (PHS act) (42 U.S.C. 264). Section 361 of the PHS act authorizes the Secretary to make and enforce such regulations as judged necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or from one State to another State. We may regulate intrastate transactions under this authority as appropriate (see State of Louisiana v. Mathews, 427 F. Supp. 174 (E.D. La. 1977)).

Section 361 of the PHS act also provides for such inspection and destruction of articles found to be so infected or contaminated as to be sources of dangerous infection to humans, and other measures, as may be deemed by the Secretary to be necessary.

We have invoked section 361 of the PHS act to regulate various activities and articles. FDA has invoked this authority, for example, to prevent the transmission of communicable disease through certain shellfish, turtles, certain birds, and human tissue intended for transplantation (see 21 CFR 1240.60 (molluscan shellfish), 1240.62 (turtles), 1240.65 (psittacine birds), and 1270.1 through 1270.43 (human tissue)). CDC has invoked section 361 of the PHS act to control the importation of dogs and cats, turtles, nonhuman primates, etiological agents, and dead bodies (see 42 CFR 71.51 through 71.55, respectively). CDC has also regulated the interstate shipment of etiologic agents under this authority (see 42 CFR part 72).

Section 368 of the PHS act (42 U.S.C. 271) provides the authority to enforce section 361 of the PHS act. Under section 368(a) of the PHS act, any person who violates a regulation prescribed under section 361 of the PHS act may be punished by imprisonment for up to 1 year (42 U.S.C. 271(a)). Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 per violation if death has not resulted from the violation or up to \$250,000 per violation if death has resulted (18 U.S.C. 3559, 3571(b)). Organizations may be fined up to \$200,000 per violation not resulting in death and \$500,000 per violation resulting in death (18 U.S.C. 3559, 3571(c)). In addition, Federal district courts have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. You should also note that if we add more animals under 21 CFR 1240.63(a)(1)(i)(H) or 42 CFR 71.56(a)(1)(i), any violation involving those additional animals would be considered to be a violation of a regulation prescribed under section 361 of the PHS act.

We are proceeding without notice and comment rulemaking because we need to have regulations in place immediately to address the monkeypox situation. Under the provisions of the Administrative Procedure Act at 5 U.S.C. 553(b)(B), we find for good cause that prior notice and comment on this rule are impracticable and contrary to the public interest. It is imperative that we act quickly to clarify and maintain restrictions on the African rodents, prairie dogs, and other animals to prevent the monkeypox virus from spreading and becoming established in the United States.

V. What Is the Environmental Impact?

FDA has determined under 21 CFR 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In the absence of an applicable categorical exclusion, the Director, CDC, has determined that provisions amending 42 CFR part 70 will not have a significant impact on the human environment. This determination is consistent with the FDA determination that the provisions in 21 CFR part 1240 are covered by a categorical exclusion.

VI. What Is the Result of the Analysis of Impacts?

We have examined the impacts of the interim final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Unless we certify that the rule is not expected to have a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act, as amended by the Small Business Regulatory Flexibility Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202 of UMRA requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100 million in any one year (adjusted annually for inflation). We have conducted analyses of the rule, and have determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes.

The interim final rule is not a significant regulatory action as defined by the Executive Order. This regulatory action is also not a major rule under the Congressional Review Act.

However, the Regulatory Flexibility Analysis concludes that the rule may have a significant impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require us to prepare a statement of costs and benefits for the interim final rule because the rule is not expected to result in any one-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation-adjusted statutory threshold is about \$110 million.

A. Objectives and Basis for the Action

Incomplete data preclude us from developing a quantitative estimate of the economic benefits or costs of this rule. However, we believe that the rule is necessary to minimize the risk of establishing and spreading the monkeypox virus. The rule formalizes an administrative ban on trade, transport, and import of certain animals and sets forth a process to obtain exemptions. In particular, the interim final rule prohibits the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release into the environment of prairie dogs and other specific animals, and it prohibits importation of African rodents. The interim final rule supersedes the June 11, 2003, order and allows permits for exemptions in cases that pose little risk of establishing or spreading the monkeypox virus.

B. The Nature of the Impacts

This rule has several impacts. It continues and clarifies the prohibition of the import of African rodents, as well as the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, and release into the environment of prairie dogs and other specific animals, but allows parties to apply for exemptions in instances that would not pose a risk of establishing or spreading the monkeypox virus. Thus, importers of small mammals would have to find animals other than African rodents

to satisfy market demands for unusual pets. Firms that supply prairie dogs and other listed animals as pets would be unable to do so and would have to switch to different animals. In addition, some animals may be destroyed if it is determined that such action is necessary to prevent the further spread of monkeypox in the United States. While we have not generated quantitative estimates of the magnitude of these effects, available evidence suggests that they are relatively small.

We invite comment on the economic analysis in support of this interim final rule.

C. Need for the Rule

A new infectious disease, if uncontrolled, can have large adverse economic effects. It does so because a single infection can lead to a few new cases, which in turn can lead to many others. Through this multiplier effect, a single uncontrolled case of a new disease may trigger an epidemic. For example, West Nile virus, a mosquito-borne zoonotic disease originally from Africa, sickened more than four thousand Americans and killed 284 in 2002 alone, although it was not recorded in the United States before 1999 (Ref. 24). West Nile virus has also affected populations of many indigenous species of birds and mammals. Existing economic incentives to control such risks are generally inadequate because the costs of such risks to third parties are not borne by the owners of infected animals.

Notwithstanding the inadequacy of incentives to control risks associated with monkeypox virus, trade in some of the animal species affected by this rule fell before any announced government action. An on-line trading service, exoticpets.com, listed on June 13, 2003, all of the advertisements to sell prairie dogs that had been posted since May 15, 2003. These data, though they represent advertised prices and not the actual prices of completed transactions at a single website, suggest that the market responded very quickly to rumors linking prairie dogs to

the monkeypox outbreak. Five announcements to sell or to buy prairie dogs as pets appeared in the 7 days beginning May 15, 2003. Three more advertisements appeared in the 7 days starting May 22, 2003, and ending May 28, 2003, with the very last announcement posted on May 27, 2003.

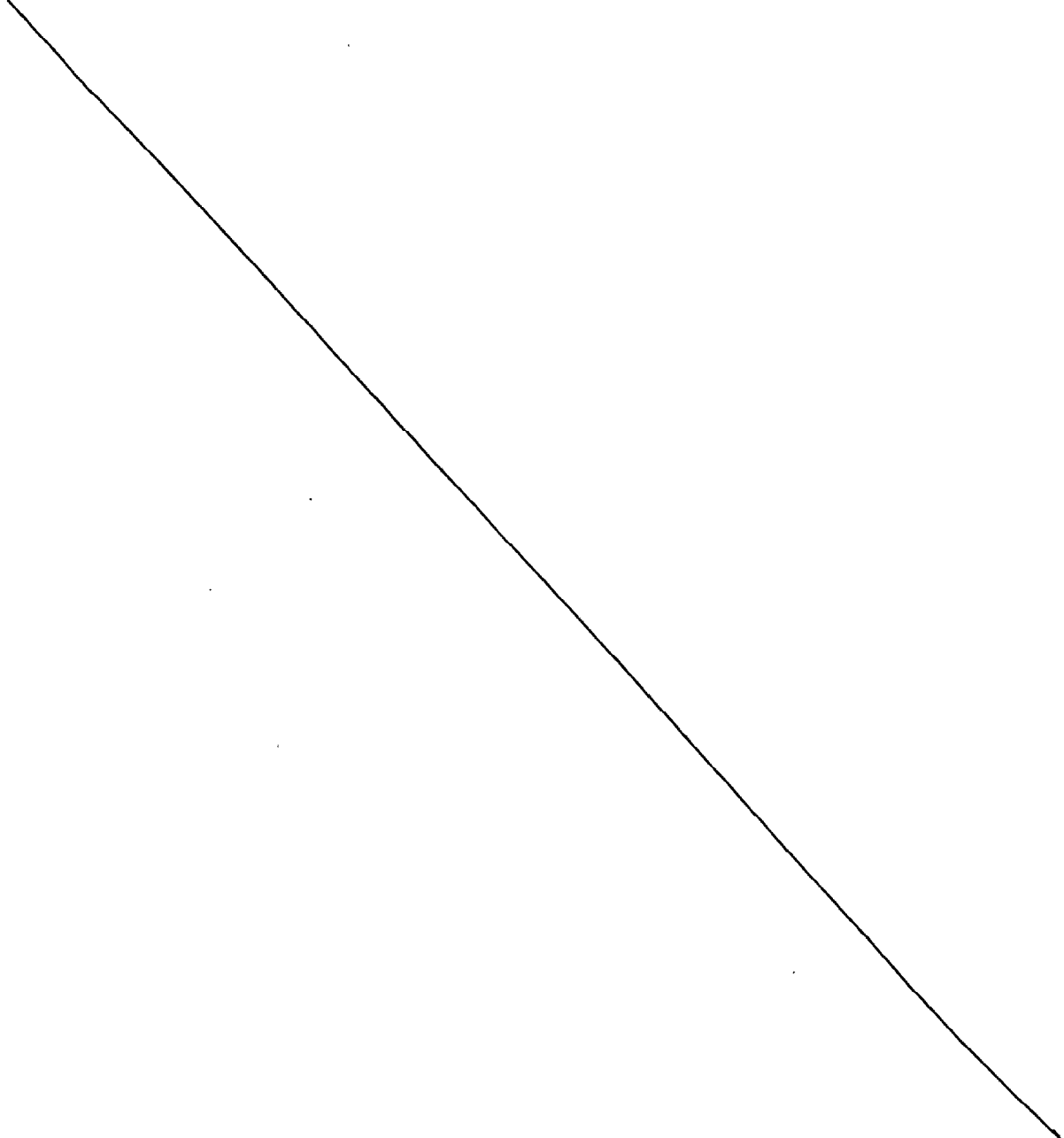
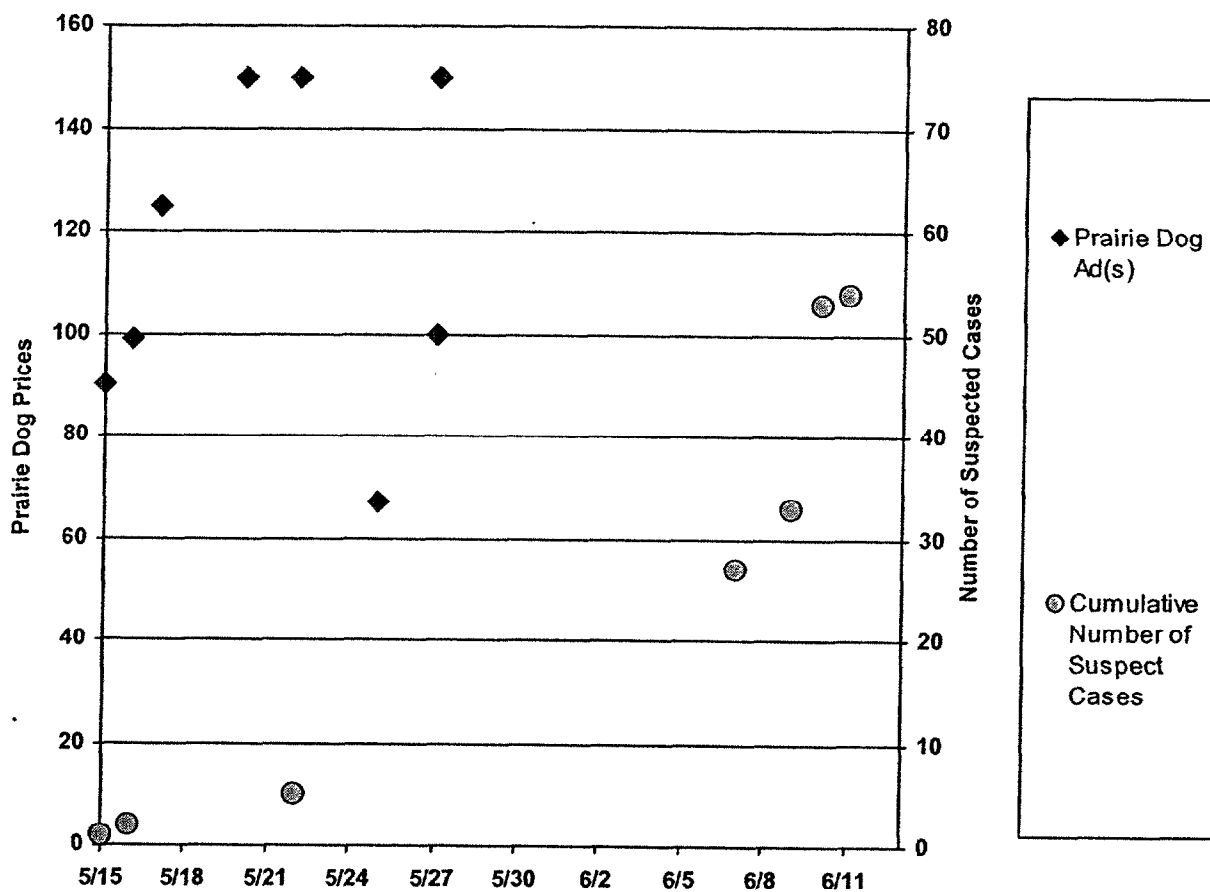


Figure 1
Advertised Prices for Prairie Dogs and
Suspected Cases of Monkeypox in the United States



The prairie dog trading market then seemed to vanish, even before the earliest report linking prairie dogs to the outbreak of monkeypox. On June 6, 2003, one day before any announcement by CDC, Wisconsin health officials banned the sale, importation, and display of prairie dogs because of human disease outbreak associated with animal-borne transmission (Ref. 25). Three notices mentioning the illness and the restrictions on trade appear at exoticpets.com in lieu of advertisements on June 8 and 9, 2003. No subsequent announcements or advertisements appear on the website. These data, summarized in Figure 1, suggest that the market reactions to risks of contaminated pets may have already curtailed most, if not all, of the retail trade.¹ Statistical testing of the prairie dog advertisement appearance rates before and after the CDC announcement shows a 99.3 percent chance that there was a real change in the daily advertisement appearance rate (i.e., the rate difference is very likely not the result of mere chance).² According to the prices listed in classified advertisements posted at exoticpets.com, neither the markets for other pets, such as rabbits, nor the frequency of such advertisements, have been affected.

While the market has responded quickly to the outbreak, it is also important to note that the market enabled the outbreak to occur in the first place. With less vigilant public health

¹ Figure 1 excludes one advertisement because it was a solicitation to buy without reference to price.

² From May 15, 2003, through May 28, 2003 (14 days inclusive), there were 8 days when advertisements for prairie dogs appeared at the web site for exoticpets.com. Thus, on about 57 percent ($8/14=0.571$) of the days, prairie dog advertisements appeared. From May 29, 2003 through June 6, 2003 (9 days inclusive), there were no (zero) days when prairie dog advertisements appeared. According to Fisher's Exact Test, the probability that these two statistics came from the same distribution is 0.0072. In other words, we are 99.3 percent certain that there was a change in the daily appearance of prairie dog advertisements between these two time periods.

surveillance, or with private parties that were less cooperative or less responsible, infected prairie dogs could have been distributed more broadly in commerce, posing greater disease risks. In addition, infected prairie dogs might have been released into the wild, posing large risks to native mammals and, through them, to humans. This rule would minimize the risks that such events could occur by requiring permits if individuals capture, transport, sell, barter, exchange, distribute, or release animals that have been implicated in the monkeypox outbreak.

D. Baseline

Economic analysis of a regulatory action requires as a first step the identification of a baseline, a depiction of the world in the absence of any action, from which to calculate the effects of the regulations. The baseline for this rule is complicated by at least two issues. First, as noted, news of the epidemic has curtailed trade in advance of Federal action. Buyers and sellers do not want to trade animals that may be infected with a virus that can make people sick. To distinguish between the effects of our actions to ban trade in certain animals and the effects of monkeypox on such trade, this analysis uses as a baseline the current state of affairs; that is, it recognizes that the outbreak is ongoing and that the market has responded.

An administrative order issued by FDA and CDC on June 11, 2003, and intended to manage the same risks as this interim final rule also complicates efforts to identify a baseline. We propose to use two baselines to provide full information about the effects of our actions. First, we assume that there is no administrative order, and second, we assume that the baseline includes the June 11, 2003, order.

With the second baseline there are no costs and no benefits because the interim rule formalizes and clarifies the June 11, 2003, order, with the important exception of a new procedure for Federal permits allowing people to import, capture, offer to capture, transport,

offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and release into the environment prairie dogs and other specific animals when it otherwise would be prohibited. Relative to the outright prohibition in the June 11, 2003, order, permits would lower costs to parties seeking to import, capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and release into the environment listed animals. For example, zoos and related animal facilities, prairie dog relocation services, and research labs may request permission to import, capture, transport, or sell listed animals, and, if permission is granted, they may continue such activities that would otherwise be prohibited by the June 11, 2003, order. Generating quantitative estimates of the cost savings from such permits is not possible because of the uncertainty associated with how and when such permits would be granted. While these exemptions may in principle pose some risks, we believe that these are negligible because permits would be granted only in instances where prohibited activities pose minimal risk of establishing or spreading the monkeypox virus.

E. Alternatives

Sound economic analysis requires an assessment of reasonable alternatives. The key alternative, and one on which we solicit comment, is a “sunset” provision ending the domestic restrictions by January, 2004, unless we made a determination that the ban was necessary to protect health and safety. The economic advantage of this alternative relative to this interim final rule may be the elimination of permitting costs for capturing, transporting, selling, bartering, exchanging, distributing, or releasing an animal that has been only a conduit and not a source of infection, as well as allowing for resumption of a prairie dog market as existed before

the disease. It may, however, provide for later capture, transport, sale, barter, exchange, distribution, or release of an animal that may carry other diseases.

We also considered whether it would be possible to devise a regulatory program that would allow for testing and certification of animals, whereby animals that had been certified to be free of the monkeypox virus would not be subject to the rule's prohibitions. We did not pursue this alternative because studies are being conducted to determine the incubation period in various animal species and the manner in which the virus may be transmitted. In other words, scientific knowledge about monkeypox is still evolving, so it may be unlikely that a quick, reliable testing method, particularly when incubation periods and the extent to which animals may be asymptomatic carriers of the monkeypox virus are unknown, will be developed in the immediate future.

Assessment of other alternatives is limited because the interim final rule would allow exceptions to the prohibited activities provided that parties have Federal permits. The specific criteria for these exceptions have not been determined, but can be expected to include those activities that pose no risk of establishing or spreading the monkeypox virus.

F. Benefits

A recent report indicates that 71 cases of monkeypox in humans have been reported in Illinois, Indiana, Kansas, Ohio, Missouri, and Wisconsin (Ref. 4). Detailed clinical information was available for 30 cases reported in Illinois and Wisconsin. Among these, the earliest reported onset of illness was on May 15, 2003. For the majority of patients (22 (73 percent)), a febrile illness has either preceded or accompanied the onset of a papular rash; respiratory symptoms (16 (64 percent)), lymphadenopathy (14 (47 percent)), and sore throat (10 (33 percent)) also were prominent signs and symptoms. The rash typically progressed through stages of vesiculation,

pustulation, umbilication, and encrustation. Early lesions became ulcerated in some patients. Rash distribution and lesions have occurred on the head, trunk, and extremities; many patients had initial and satellite lesions on palms, soles, and extremities. Rashes were generalized in some patients. No fatalities have yet been reported in the United States although the case fatality rate in remote and medically underserved areas of Africa is between 1 percent and 10 percent (Ref. 26).

We lack data to estimate the value in monetary terms that people might assign to specific reductions in the risk of monkeypox infections.

This rule would also reduce the risk to public health that would result if monkeypox became endemic in the United States. (An “endemic” disease is one that is confined to or characteristic of a particular locality.) The potential risks to humans from exposure to monkeypox established among wild animal populations would be potentially large if the disease were not controlled. Inadvertent contact between infected pets and wild animals could spread monkeypox into established wild animal populations, causing widespread disruption to ecosystems and potentially exposing large numbers of people to a new infectious agent. In Africa, serologic evidence of monkeypox infection has been found in a wide variety of nonhuman primates, rodents, and squirrels; monkeypox virus has been isolated from a species of squirrel in Zaire, but the role of any particular species as a reservoir has not been established. Some species of primates, rodents, and lagomorphs (such as rabbits) are known to be susceptible. Although no infections have been previously reported in dogs or cats, these species may also be susceptible to monkeypox (Ref. 27). Thus, there is significant risk that common, native mammalian species, such as squirrels and rabbits, could become reservoirs of this new disease if it were released into the environment. CDC has reported that a pet rabbit treated at a

veterinary clinic that also had an infected prairie dog became ill and died. The rabbit died spontaneously, but the owner of that rabbit became ill with a disease compatible with the clinical description of monkeypox; however, the rabbit owner was not a laboratory-confirmed case (Ref. 28). This rule would reduce the risk of the monkeypox virus spreading among both species known to carry it, as well as the possibility of it spreading through wild and pet species currently not known to carry it.

Because this interim final rule would be expected to reduce the frequency of monkeypox outbreaks, there would also be a commensurate reduction in outbreak traceback efforts by the Federal Government, as well as possible state and local government efforts. The costs of these traceback efforts would vary depending on the size of the outbreak.

G. Costs

The costs of this interim rule are the lost value to consumers and producers associated with not being able to import, capture, transport, sell, barter, exchange, distribute, or release prairie dogs and certain African rodents. We believe that the costs are not likely to be high, because the monkeypox outbreak has already sharply curtailed the trade in prairie dogs, as described above. This curtailment occurred prior to Federal regulatory action. Unfortunately, we lack data on the magnitude of trade that has occurred since the outbreak was publicized in June, and so we present instead data from before the outbreak. These data overstate the costs of the rule insofar as they ignore the reduction in volume of trade likely already to have resulted from the outbreak itself. Indeed, if the data shown in Figure 1 are representative of broader and long-lasting market conditions, then the interim final rule's prohibition has no impact on sales of prairie dogs as pets because trade has vanished as a result of the outbreak. If the trade in prairie dogs would otherwise have resumed in the absence of this order, then costs would occur.

Although we do not have trade data for the other listed animals during the same periods, we surmise that similar reductions in trade of these animals has also occurred.

Generally, the trade in prairie dogs falls into several categories. In terms of volume, the largest category with the greatest number of animals traded involves the market for pets. There are currently about 10 to 15 million prairie dogs in the United States (Ref. 29). In 2001, 30,000 prairie dogs were sold for pets (Ref. 30). About 15,000 of the 30,000 sold were captured in Texas by registered dealers (Ref. 31). Some 15,000 are exported annually (Ref. 29). Sales over the last few years have remained relatively constant, with sales and prices slightly down since Japan, the largest foreign market, banned importation of prairie dogs on March 1, 2003.

Typically, pet stores purchase prairie dogs from dealers for \$50 to \$60 each, and re-sell to pet owners for about \$150 each (Ref. 32). If average retail prices of prairie dogs were \$150 prior to the monkeypox outbreak, annual prairie dog sales in the pet market would appear to be \$4.5 million, although this estimate must be seen as very approximate because it is based on a market survey.

A ban on the capture, transport, sale, barter, exchange, distribution, or release of prairie dogs would have a noticeable effect on prairie dog trappers who supply the pet market, if it occurred in the absence of an outbreak. Prairie dog trappers would not be expected to incur serious economic effects this year because the peak of the prairie dog sales season (April through June 1) has passed (Ref. 32). A permanent prohibition on transportation of prairie dogs, however, could have a very serious effect. Suppliers of pet supplies and equipment intended for prairie dogs and the other small, listed rodents may also be affected by this action, but we believe such effects will be small because this equipment may also be suitable for some other mammalian pets, such as hamsters or guinea pigs.

A variety of relocation activities involving prairie dogs are undertaken in part because the Federal Fish and Wildlife Service has assigned at least one prairie dog species a status of “warranted” under the Endangered Species Act. Many of these activities already require permits from State agencies (Ref. 33). We lack information on the scope or magnitude of such activities or how they might be affected by the June 11, 2003, order or by this rule, but would expect some of them to qualify for exemptions.

Another category of trade affected by this rule is zoos, which routinely trade animals for a variety of purposes, although we lack information about the extent of trade in prairie dogs or African rodents. The American Zoo and Aquarium Association (AZA) is the largest zoo and aquarium organization in the world. The AZA’s mission is to establish, uphold, and raise the highest zoological and aquarium industry standards. It has accredited over 200 organizations, of which about 170 are zoos in the United States. As of June 6, 2003, about 79 zoos in the United States held 758 prairie dogs according to a survey of data at the website for the International Species Information System.³ We recognize that AZA has an accreditation process for institutions such as zoological parks, and a separate certification process for related facilities, such as wildlife refuges, conservation research facilities, survival or rehabilitation centers, breeding farms, and educational organizations (Ref. 34). AZA accreditation requires that

³ The International Species Information System (ISIS) maintains a computer-based information system for wild animal species held in captivity. The database contains information on ten thousand species held in 586 institutions in 72 countries on 6 continents. Roughly 250 of these institutions are professionally managed United States zoos, most of which have been accredited by AZA. The ISIS Web site allows web-based searches by species and is updated weekly (see International Species Information System (ISIS); conversation with Mr. Nate Flesness, ISIS director; ISIS Web site information (www.ISIS.org)). ISIS is located in Apple Valley, Minnesota.

institutions follow the guidelines of the American Association of Zoo Veterinarians regarding medical programs and zoo hospitals.

Data on the sale and imports of the other rodents that would be prohibited with this interim rule are limited. Data from the U.S. International Trade Commission show that about \$38,000 worth of live African animals that could reasonably be expected to include these specific rodents were imported into the United States in 2002. Information from the Fish and Wildlife Service indicates that, in 2002, nearly 8,000 African rodents were imported into the United States. We do not have information that confirms that these separate database measurements relate to the same animals, but suggest that African rodent imports appear to be relatively small. Retail sales of such animals as pets would be expected to be somewhat higher than the value shown above due to retailer price markups. Further, we are unable to confidently estimate the number of other listed animals (except for prairie dogs) from either domestic or imported origin that are sold each year as pets in the United States. A recent American Pet Products Manufacturers Association survey does not list any of the animals listed in this interim final rule in its section on small animals (Ref. 35). Accordingly, we conclude that the number of such animals is relatively small.

The interim final rule would allow for persons wishing to seek exemptions from the rule's prohibitions by requesting written permission from FDA or CDC. We have tentatively estimated that about 60 such requests would be made annually to FDA. We would expect these requests to be made by animal relocation specialists or others involved in biological research or conservation efforts. These requests are estimated to take 2 hours to complete. We cannot confidently estimate an average wage for those seeking permission to transport listed animals, but at a total annual burden of about 120 hours, we would expect the total cost burden to range

from \$3,000 to \$6,000. FDA resource costs to process and respond to each request are estimated to total about 6 hours distributed across various staff levels. We estimate that the average pay level of these staff positions at about \$37 per hour. The administrative effort to process these requests would result in about \$13,300 (60 requests x 6 hours per request x \$37 per hour = \$13,320) in costs to FDA.

Similar costs would be incurred by those that would request written permission from CDC to import a listed animal. We estimate that CDC would receive about 12 requests annually, resulting in a cost burden of about \$500 to these individuals. CDC would also be expected to incur administrative costs to process and respond to these requests that would be similar to those incurred by FDA. We estimate that those costs may total to about \$3,000.

This interim final rule may result in the quarantine and/or destruction of an unknown number of listed animals if we determine that such action is necessary to prevent the further spread of monkeypox in the United States. We do not have an estimate of the marginal cost to quarantine, destroy or dispose of an individual animal. Further, the uncertainty surrounding the total number of animals that would be affected by this provision of the rule makes it difficult to estimate a total cost for such circumstances. We believe that facilities for such purposes are available and would not be expected to impose substantial costs to the Government.

1. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities if that rule may have a significant impact on a substantial number of small entities.

a. Objective of the rule. The implementation of this interim final rule would ensure the safety of the human and animal populations in the United States from the monkeypox virus. The

objective of this interim final rule is to reduce the risk to public health from the spread of the monkeypox virus throughout the United States.

b. Small entity definitions and impacts. A regulatory flexibility analysis (RFA) is required to estimate the number of small entities to which the interim final rule would apply. This rule would affect importers of African rodents, trappers and distributors of prairie dogs, other small animal distributors, as well as retail pet stores.

The Small Business Administration (SBA) sets criteria by which it qualifies businesses as small entities. The SBA limit for small pet and pet supply stores is \$6 million in revenues. Census Bureau data shows that about 6,500 retail pet store companies operate about 8,300 establishments in the United States. A substantial number of these firms (about 94%) have a single establishment with average annual revenues of about \$356,000, thereby qualifying them as small businesses. We believe it is unlikely that the total sales of all of the listed animals would represent a significant portion of total pet store sales. However, due to the lack of data on total sales of these animals, as well as the possibility that some pet stores may specialize in the small animals that are listed in this rule, we cannot rule out the possibility that the rule may have a significant impact on a substantial number of these small entities.

The SBA limit for small business qualification for trappers is \$3.5 million or less in revenues. Prairie dog trappers, as described previously, would surely qualify as small businesses under this definition (Ref. 32). For at least some of these trappers, the loss of their profits from the effects of this rule would likely represent a significant impact on their businesses.

The SBA limit for all small business wholesale activities is set at 100 employees. We lack the data to determine the extent to which wholesalers and distributors of all small animals listed in this interim final rule (including those that import animals and those that handle

domestic animals) would be affected by this rule. That being the case, we allow for the possibility that a substantial number of those that are affected may be small entities, and in some instances may incur significant impacts due to this rule.

We request public comment on the size and structure of those firms or persons involved in the trade of all animals listed in this interim final rule and the rule's effects on such firms and persons. The incompleteness of data, as described previously, precludes us from developing quantitative estimates of the costs of this rule for each type of small entity.

2. Analysis of Alternatives

As stated previously, one alternative is a "sunset" provision ending the prohibitions on prairie dogs or other animals at some point in the future, unless we determine that the ban was necessary to protect health and safety. The economic advantage of this alternative relative to this interim final rule may be the elimination of permitting costs for transport in domestic animals in the case that monkeypox has not become endemic. It may, again, provide for later capture, transport, sale, barter, exchange, distribution, or release of an animal that may carry other diseases. This alternative was not accepted because of the uncertainty in predicting when a ban would no longer be necessary.

A second alternative would have been to allow the continued capture, transport, sale, barter, exchange, distribution, or release of the listed animals, effectively doing nothing to reduce the risk of further spread of monkeypox. Although the market for at least prairie dogs was apparently greatly reduced due to public knowledge of the monkeypox issue and seasonal variation in the prairie dog market, this option would have allowed those few in the market that dismissed the severity of the problem to continue to pose a risk that monkeypox would become

endemic to domestic pets and wildlife and further affect human health. For this reason it was determined to be not acceptable.

A third alternative would have been to exempt small businesses from this interim final rule. However, because about 94 percent of pet stores and probably a large portion of small animal trappers and wholesalers/distributors are small businesses, this option would have compromised the rule's ability to reduce the risk of establishing or spreading the monkeypox virus in the United States.

VII. Paperwork Reduction Act of 1995

This interim final rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Both FDA and CDC have requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). Such emergency processing is necessary in order to respond immediately to the monkeypox outbreak. This interim final rule, at 21 CFR 1240.63(a)(2)(ii)(A) and (B) and 42 CFR 71.56(a)(2)(i) and (ii), contains information collection requirements. In compliance with the PRA (44 U.S.C. 3507(d)), we have submitted a copy of the information collection provisions of this interim final rule to OMB for review.

The information collections in this interim final rule have been approved under OMB control number 0910-0519 (for 21 CFR 1240.63) and OMB control number 0920-0615 (for 42

CFR 71.56). An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it contains a currently valid OMB control number.

Title: Control of Communicable Diseases; Requests for Exemptions from the Restrictions on African Rodents, Prairie Dogs, and Certain Other Animals.

Description: Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that infected rodents are capable of transmitting the monkeypox virus to humans. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa. It is likely the virus is entering the United States by way of rodent species imported from Africa. Further transmission of the virus likely occurred in the storage and handling of these rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic prairie dogs in this country housed in the same animal-holding facility or pet shop. Introduction of exotic species, such as African rodents, poses a serious public health threat because of the potential of human monkeypox virus infection. Transport, sale, or any other type of distribution, including release into the environment, of certain species of rodents poses a serious public health threat because of the potential for further spread of the monkeypox virus to other animal species and to humans. To prevent the establishment and spread of the monkeypox virus in the United States, we are prohibiting the capture, offer to capture, transport, offer to transport, sale, barter, or exchange, offer to sell, barter, or exchange, distribution, offer to distribute, or release into the environment of prairie dogs and certain rodents and any other animal so prohibited by order of the Commissioner of Food and Drugs. We are also prohibiting the importation of all rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or any other animal whose importation the Director of CDC has prohibited by order. The rule provides for

exemptions from these prohibitions and discusses our authority to issue orders causing an animal to be quarantined, re-exported, or destroyed. The information collection burden is associated with the process for seeking an exemption.

Description of Respondents: Persons who capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, import, offer to import, or release into the environment certain rodents.

TABLE 1.--ESTIMATED ANNUAL REPORTING BURDEN ¹

| CFR Section | No. of Respondents | Annual Frequency per Response | Total No. of Responses | Hours per Response | Total Hours |
|--|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 21 CFR 1240.63(a)(2)(ii) (A) and (B) | 60 | 1 | 60 | 2 | 120 |
| 42 CFR 71.56(a)(2)(i) and (ii) | 12 | 1 | 12 | 0.5-1.0 | 10 |
| | | | | Total | 130 |

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on our experience to date with the June 11, 2003, order and on similar requests under FDA regulations. To estimate the number of respondents, we examined the number of requests and inquiries we have received since the June 11, 2003, order. Both FDA and CDC have received fewer than 10 requests, and most requests involved requests to move an animal from one location to another. (FDA also has received many inquiries.) As we cannot predict how the monkeypox outbreak will be resolved, we will tentatively estimate that there will be 60 respondents for FDA's provisions and 10 respondents for CDC's provisions. Furthermore,

based on FDA's experience with submissions seeking exemptions or waivers, we will tentatively estimate that each respondent will need 2 hours to complete its request for an exemption.

Therefore, the total reporting burden under 21 CFR 1240.63(a)(2)(ii)(A) and (B) will be 120 hours (60 respondents x 2 hours per response = 120 hours).

CDC's estimates for the burden of its data collection are based on its experience with the importation of non-human primates. CDC estimates that there will be 12 respondents annually for this data collection. Respondents will include individuals, businesses, and organizations. Although CDC estimates that most respondents will submit only one request per year, CDC feels that organizations may submit 2 requests per year. Individuals and businesses submitting requests will need 30 minutes to prepare the request. Organizations will need 1 hour to prepare an initial request and 10 minutes for subsequent requests. The total annualized burden under 42 CFR 71.56(a)(2)(i) and (ii) will be 10 hours.

The requirements contained in 21 CFR 1240.63(c) and 42 CFR 71.56(c) are not subject to review by OMB because they are exempted under 5 CFR § 1320(a)(4), which exempts "administrative actions * * * involving an agency against specific individuals or entities."

VIII. Federalism

We have analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132 and have determined that the rule has federalism implications. Federal restrictions on the capture, offering to capture, transport, offering to transport, sale, barter, or exchange, or offering to sell, barter, or exchange, distribution, offering to distribute, or release into the environment of certain rodents and prairie dogs are both necessary and appropriate to prevent the establishment and spread of monkeypox virus in the United States. In accordance with section 361(e) of the PHS act (42 U.S.C. 264(e)), nothing in this interim final rule

supersedes any provisions of State or local law except to the extent that such a provision conflicts with this interim final rule. For example, the interim final rule does not prevent a State from taking stronger measures to deal with infected or possibly infected animals or to cover additional species. Furthermore, while some States have issued orders with restrictions that cover fewer animal species, those State requirements do not conflict with the interim final rule and would also not be superseded. However, in accordance with section 361(e) of the PHS act, any State or local law that would permit any activity prohibited under this interim final rule would be in conflict with this rule and, therefore, would be superseded.

We note that we have been in direct contact with many States regarding the June 11, 2003, order and efforts to prevent the spread of monkeypox. We believe that the public health requires us to give this regulation immediate effect. Through this interim final rule, and under to section 4(e) of Executive Order 13132, we are providing all affected State, local, and tribal officials notice and opportunity to participate in this rulemaking.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Khodakevich, L., Jezek, Z. and Messinger, D., "Monkeypox Virus: Ecology and Public Health Significance," Bulletin of the World Health Organization, 66: 747-752, 1988.

This reference identifies several species of squirrels as playing a major role as a reservoir for the monkeypox virus.

2. Centers for Disease Control and Prevention, "Updated Interim Case Definition for Human Case of Monkeypox," dated July 2, 2003 (available through www.cdc.gov/ncidod/monkeypox). FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the FEDERAL REGISTER.

3. Centers for Disease Control and Prevention, "Questions and Answers About Monkeypox," dated July 7, 2003 (available through www.cdc.gov/ncidod/monkeypox).

4. Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Monkeypox--Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003," Morbidity and Mortality Weekly Report, 52: 642-646 (July 11, 2003)

5. State of Colorado, Wildlife Commission, "Emergency Regulation," dated July 10, 2003.

6. State of Illinois, "Executive Order in Response to Orthopox Outbreak," dated June 7, 2003.

7. State of Indiana, Board of Animal Health, Emergency Rule, dated June 9, 2003.

8. State of Michigan, Department of Community Health, "Order Finding Imminent Danger to the Public Health and Requiring Corrective Action," dated June 13, 2003, and later amended on June 27, 2003.

9. State of North Dakota, State Board of Animal Health, "In the matter of: Monkeypox in Prairie Dogs and Gambian Giant pouched Rats," Order No. 2003-04, dated June 11, 2003.

10. State of Wisconsin, Department of Agriculture, Trade, and Consumer Protection, "Emergency Rule," dated June 9, 2003.

11. State of Wisconsin, Department of Health and Family Services, "Emergency Order - June 12, 2003," dated June 12, 2003.

12. Order dated June 11, 2003, signed by Julie Louise Gerberding, Director, Centers for Disease Control and Prevention, and Mark B. McClellan, Commissioner of Food and Drugs, titled "Joint Order of the Centers for Disease Control and Prevention and the Food and Drug Administration, Department of Health and Human Services."

13. 68 FR 36566, June 18, 2003.

14. Centers for Disease Control and Prevention, "Update: Multistate Outbreak of Monkeypox-- Illinois, Indiana, Kansas, Missouri, Ohio, and Wisconsin, 2003," Morbidity and Mortality Weekly Report 52: 616-618, July 4, 2003, (describing how animal laboratory testing demonstrated that a Gambian giant pouched rat, three dormice, and two rope squirrels from an April 9, 2003, shipment of animals from Ghana were infected with the monkeypox virus).

15. North Carolina Department of Health and Human Services, "State Health Official Reminds Public Not to Release Prairie Dogs Into the Wild," dated June 19, 2003.

16. Colorado Division of Wildlife, "Wildlife Report: Black-Footed Ferrets Back in Colorado," dated November 19, 2001 (available at www.dnr.state.co.us/cdr_news/wildlife/2001111985112.htm).
17. Food and Drug Administration and Centers for Disease Control and Prevention, "Wild-to-Wild Translocation or Transportation of Prairie Dogs" (undated).
18. Centers for Disease Control and Prevention, "Interim Guidance to State and Local Governments for the Removal of State- and Locally Imposed Quarantine Orders and the Euthanasia of Animals Affected by the Monkeypox Outbreak," dated July 1, 2003.
19. Centers for Disease Control and Prevention, "Questions and Answers: Quarantine and Euthanasia of Animals Affected by the Monkeypox Outbreak," dated July 10, 2003.
20. Fish and Wildlife Service, "Notice to the Wildlife Import/Export Community," dated June 11, 2003 (describing import and export prohibitions on certain rodents, including any rodents from Africa, whether alive or dead, for any purpose).
21. Peeters, M., et al., "Risk to Human Health from a Plethora of Simian Immunodeficiency Viruses in Primate Bushmeat," Emerging Infectious Diseases, 8: 451-457 (May, 2002) (showing that humans who hunt and handle bushmeat are exposed to many viruses).
22. Downie, A.W., and Dumbell, K. R., "Survey of Variola Virus in Dried Exudate and Crusts from Smallpox Patients," Lancet, 1: 550-3, 1947.
23. Woodruffe, G. M., "The Heat Inactivation of Vaccinia Virus," Virology, 10: 379-82 (1960).
24. <http://www.cdc.gov/od/oc/media/wncount.htm>.
25. Wisconsin Division of Public Health, Press Release: "6/6/03, Wisconsin Division of Public Health Bans Sale of Prairie Dogs."

26. Centers for Disease Control and Prevention, "Multistate Outbreak of Monkeypox - Illinois, Indiana and Wisconsin," Morbidity and Mortality Weekly Report, 52: 537-540, June 13, 2003.

27. Centers for Disease Control and Prevention, "Monkeypox Infections in Animals: Updated Interim Guidance for Veterinarians," dated July 22, 2003 (available through <http://www.cdc.gov/ncidod/monkeypox/pdf/mpoxanimalguidance.pdf>).

28. Centers for Disease Control and Prevention, "CDC Telebriefing Transcript: Monkeypox Investigation," dated June 7, 2003 (available through <http://www.cdc.gov/od/oc/media/transcripts/t030607.htm>).

29. Data Source: "Pet Your Prairie Dog," Wall Street Journal, posted April 24, 2003. This article can be found at <http://www.twincities.com/mld/twincities/living/5698532.htm>.

30. Data Source: http://www.prairiedog.info/prairie_dog_reintroduction.htm.

31. Robert E Pierre, "Newfound Scrutiny for a Pest to Some, a Beloved Pet to Others," Washington Post, June 11, 2003. Page A-03.

32. Phone conversation with prairie dog trapper in Lubbock, Texas, on June 16, 2003.

33. U.S. Fish and Wildlife Service, Mountain-Prairie Region, "Black Tailed Prairie Dog-The Black-tailed Prairie Dog Conservation Assessment and Strategy," dated September 9, 1999 (available through <http://www.r6.fws.gov/btprairiedog/conasssstrat.htm#strategy>).

34. <http://www.aza.org/Accreditation/#acc>.

35. 2003 2004 QPPMA National Pet Owners Survey, American Pet Product

36. Axtman, K., "The Prairie Dog: Pest or Pet?," The Christian Science Monitor, August 13, 2002, taken from the web on June 12, 2003, from <http://www.csmonitor.com/2002/0813/p03s01-usgn.html>.

37. Exotic Pets.com, taken from http://www.exoticpets.com/Show_Ads.asp?petid=16 on June 12, 2003.

38. Hutin, Y. J. F., et al., "Outbreak of Human Monkeypox, Democratic Republic of Congo, 1996-1997," Emerging Infectious Diseases, 7:434-438 (May through June, 2001).

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 1240

Communicable diseases, Public health, Travel restrictions, Water supply.

42 CFR Part 71

Airports, Animals, Communicable diseases, Harbors, Imports, Pesticides and pests, Public health, Quarantine, Reporting and recordkeeping requirements.

Therefore, under the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs and to the Director, Centers for Disease Control and Prevention, 21 CFR ^{parts}16 and 1240 and 42 CFR ^{part}71 are amended as follows:

Kent Giles
10-29-03
OFR

21 CFR CHAPTER I

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG

ADMINISTRATION

1. The authority citation for 21 CFR Part 16 continues to read as follows:

AUTHORITY: 15 U.S.C. 1451-1461; 21 U.S.C. 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201-262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for

§ 1240.63(c)(3) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

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OFR
K. Giles
10-29-03

§ 1240.63(c)(3), relating to a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed.

* * * * *

PART 1240—CONTROL OF COMMUNICABLE DISEASES

3. The authority citation for 21 CFR part 1240 continues to read as follows:

AUTHORITY: 42 U.S.C. 216, 243, 264, 271.

4. Section 1240.63 is added to subpart ^D~~C~~ to read as follows:

§ 1240.63 African rodents and other animals that may carry the monkeypox virus

(a) What Actions Are Prohibited? What Animals Are Affected?

(1) Except as provided in paragraph (a)(2) of this section,

(i) You must not capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, or release into the environment, any of the following animals, whether dead or alive:

- (A) Prairie dogs (Cynomys sp.),
- (B) African Tree squirrels (Helioscirus sp.),
- (C) Rope squirrels (Funisciurus sp.),
- (D) African Dormice (Graphiurus sp.),

Kent Giles
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- (E) Gambian giant pouched rats (Cricetomys sp.),
- (F) Brush-tailed porcupines (Atherurus sp.),
- (G) Striped mice (Hybomys sp.), or
- (H) Any other animal so prohibited by order of the Commissioner of Food and Drugs

because of that animal's potential to transmit the monkeypox virus; and

(ii) You must not prevent, or attempt to prevent, the Food and Drug Administration (FDA) from causing an animal to be quarantined or destroyed under a written order for the animal's quarantine or destruction.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you:

(i) Transport an animal listed in paragraph (a)(1) of this section, or covered by an order by the Commissioner of Food and Drugs, to veterinarians or animal control officials for veterinary care, quarantine, or destruction purposes; or

(ii) Have written permission from FDA to capture, offer to capture, transport, offer to transport, sell, barter, or exchange, offer to sell, barter, or exchange, distribute, offer to distribute, and/or release into the environment an animal listed in paragraph (a)(1) of this section, or covered by an order by the Commissioner of Food and Drugs. You may not seek written permission to sell, barter, or exchange, or offer to sell, barter, or exchange, as a pet, an animal listed in paragraph (a)(1) of this section or covered by an order by the Commissioner of Food and Drugs.

(A) To obtain such written permission from FDA, you must send a written request to the Division of Compliance (HFV-230), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, Attn: Listed Animal Permit Official.

You may also fax your request to the Division of Compliance (using the same address in ~~the previous sentence~~ paragraph (a)(1)(i)(A) at 301-827-1498.

Kent
Giles
10-29-6

(B) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States.

(C) We (FDA) will respond, in writing, to all requests, and we also may impose conditions in granting an exemption.

(b) What Actions Can FDA Take?

(1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

- (i) Issue an order causing an animal to be placed in quarantine,
- (ii) Issue an order causing an animal to be destroyed, or
- (iii) Take any other action necessary to prevent the spread of the monkeypox virus.

(2) Any order to cause an animal to be placed in quarantine or to cause an animal to be destroyed will be in writing.

(c) How Do I Appeal an Order?

(1) If you receive a written order to cause an animal to be placed in quarantine or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and

be submitted to the Food and Drug Administration District Director whose office issued the order, and you must submit the appeal within two business days after you receive the order.

(2) As part of your appeal, you may request an informal hearing. Your appeal must include specific facts showing there is a genuine and substantial issue of fact that requires a hearing.

(3) If we grant your request for an informal hearing, we will follow the regulatory hearing requirements at in part 16, except that:

(i) The written order will serve as notice of opportunity for that hearing, for purposes of § 16.22(a) *of this chapter*

Kent Giles
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(ii) The presiding officer will issue a decision rather than a report and a recommended decision. The presiding officer's decision constitutes final agency action.

42 CFR CHAPTER I

PART 71—FOREIGN QUARANTINE

5. The authority citation for 42 CFR part 71 continues to read as follows:

AUTHORITY: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243), secs. 361-369, PHS Act, as amended (42 U.S.C. 264-272).

6. Section 71.56 is added to subpart F read as follows:

§ 71.56 African rodents and other animals that may carry the monkeypox virus.

(a) What Actions Are Prohibited? What Animals Are Affected?

(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section,

(i) You must not import or attempt to import any rodents, whether dead or alive, that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, any products

derived from such rodents, any other animal, whether dead or alive, whose importation the Director has prohibited by order, or any products derived from such animals; and

(ii) You must not prevent or attempt to prevent the Centers for Disease Control and Prevention (CDC) from causing an animal to be quarantined, re-exported, or destroyed under a written order.

(2) The prohibitions in paragraph (a)(1) of this section do not apply if you have written permission from CDC to import a rodent that was obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or an animal whose importation the Director has prohibited by order.

(i) To obtain such written permission from CDC, you must send a written request to Division of Global Migration and Quarantine, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd., Atlanta, GA 30333. You may also fax your request to the Division of Global Migration and Quarantine (using the same address in *the previous sentence* paragraph (a)(2)(ii) at 404-498-1633.

(ii) Your request must state the reasons why you need an exemption, describe the animals involved, describe the number of animals involved, describe how the animals will be transported (including carrying containers or cages, precautions for handlers, types of vehicles used, and other procedures to minimize exposure of animals and precautions to prevent animals from escaping into the environment), describe any holding facilities, quarantine procedures, and/or veterinarian evaluation involved in the animals' movement, and explain why an exemption will not result in the spread of monkeypox within the United States. Your request must be limited to scientific, exhibition, or educational purposes.

(iii) We will respond in writing to all requests, and we also may impose conditions in granting an exemption. If we deny your request, you may appeal that denial. Your appeal must be in writing and be submitted to the CDC official whose office denied your request, and you must submit the appeal within two business days after you receive the denial. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

(3) The prohibitions in paragraph (a) of this section do not apply to products derived from rodents that were obtained, directly or indirectly, from Africa, or whose native habitat is Africa, or products derived from any other animal whose importation the Director has prohibited by order if such products have been properly processed to render them noninfectious so that they pose no risk of transmitting or carrying the monkeypox virus. Such products include, but are not limited to, fully taxidermied animals and completely finished trophies; and they may be imported without written permission from CDC.

(b) What Actions Can CDC Take?

(1) To prevent the monkeypox virus from spreading and becoming established in the United States, we may, in addition to any other authorities under this part:

- (i) Issue an order causing an animal to be placed in quarantine,
- (ii) Issue an order causing an animal to be re-exported,
- (iii) Issue an order causing an animal to be destroyed, or
- (iv) Take any other action necessary to prevent the spread of the monkeypox virus.

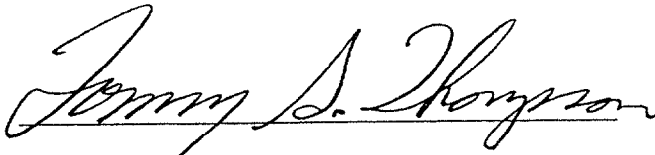
(2) Any order causing an animal to be quarantined, re-exported, or destroyed will be in writing.

(c) How Do I Appeal an Order?

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If you received a written order to quarantine or re-export an animal or to cause an animal to be destroyed, you may appeal that order. Your appeal must be in writing and be submitted to the CDC official whose office issued the order, and you must submit the appeal within 2 business days after you receive the order. Your appeal must state the reasons for the appeal and show that there is a genuine and substantial issue of fact in dispute. We will issue a written response to the appeal, which shall constitute final agency action.

Dated: OCT - 6 2003.



Tommy G. Thompson,
Secretary of Health and Human Services.

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